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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

AMERICAN REGENT, INC.,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 24-cv-11122
)	(Consolidated 24-cv-7791)
)	
RK PHARMA, INC.,)	
)	
Defendant.)	

ANSWER & AFFIRMATIVE DEFENSES OF RK PHARMA, INC.

Defendant RK Pharma, Inc., by and through its counsel, hereby respond to the allegations set forth in Plaintiff American Regent, Inc. (“ARI”) Complaint for Patent Infringement. This Answer is based on the RK Pharma’s current knowledge as to its own activities, and on information and belief as to the activities of others. If not specifically admitted herein, the allegations of the Complaint are denied. The headings in Plaintiffs Complaint are copied herein for convenience only, and any allegations in such headings are denied.

NATURE OF THIS ACTION

1. **ANSWER:** Defendant admits that this action purports to arise under the patent laws of the United States, 35 U.S.C. § 100 et. seq., arising from the RK Pharma's submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application No. 218536 ("the ANDA") which contained a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certification") seeking approval to engage in the commercial manufacture, use, or sale of generic versions of ARI's Selenious acid products ("the ANDA Products") prior to the expiration of United States Patent No. 12,150,957 ("the '957 patent"). Defendant is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1 of the Complaint and therefore denies them.

THE PARTIES

2. **ANSWER:** On information and belief, and based upon the Complaint filed in this case, ARI is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 5 Ramsey Road, Shirley, New York 11967. Defendant is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 of the Complaint and therefore denies them.
3. **ANSWER:** Paragraph 3 states a legal conclusion to which no response is required. To the extent an answer is required, Defendant RK Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 401 N. Middletown Road, Building 215/215A, Pearl River, New York 10965. RK Pharma also notes that it is the only defendant in this Action. RK Pharma denies any remaining allegations.

JURISDICTION AND VENUE

4. **ANSWER:** Paragraph 4 states a legal conclusion to which no response is required. To the extent an answer is required, Defendant RK Pharma will not contest subject matter jurisdiction solely for the purposes of Plaintiffs' Complaint in this action only. RK Pharma denies any remaining allegations.
5. **ANSWER:** Paragraph 5 states a legal conclusion to which no response is required. To the extent an answer is required, RK Pharma will not contest personal jurisdiction solely for the purposes of Plaintiffs' Complaint in this action only. With respect to any remaining allegations of Paragraph 5, RK Pharma denies the same.
6. **ANSWER:** Paragraph 6 states a legal conclusion to which no response is required. To the extent an answer is required, RK Pharma will not contest personal jurisdiction in New Jersey solely for the purposes of Plaintiffs' Complaint in this action only. RK Pharma denies any remaining allegations.
7. **ANSWER:** Paragraph 7 states a legal conclusion to which no response is required. To the extent an answer is required, RK Pharma will not contest personal jurisdiction in New Jersey solely for the purposes of Plaintiffs' Complaint in this action only. RK Pharma denies any remaining allegations.
8. **ANSWER:** RK Pharma is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products. To the extent an answer is required, Defendant denies any remaining allegations of Paragraph 8.
9. **ANSWER:** Paragraph 9 states a legal conclusion to which no response is required. To the extent an answer is required, RK Pharma will not contest personal jurisdiction in

New Jersey solely for the purposes of Plaintiffs' Complaint in this action only. RK Pharma admits that it also did not contest jurisdiction in 24-cv-1169 in this District on the same patent for that case only. RK Pharma denies any remaining allegations.

10. ANSWER: Paragraph 10 states a legal conclusion to which no response is required. To the extent an answer is required, RK Pharma will not contest personal jurisdiction solely for the purposes of Plaintiffs' Complaint in this action only. With respect to any remaining allegations of Paragraph 10, RK Pharma denies the same.

11. ANSWER: Paragraph 11 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, RK Pharma admits only that it will not contest venue for the purposes of this action only. With respect to any remaining allegations of Paragraph 11, RK Pharma denies the same.

12. ANSWER: Paragraph 12 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, RK Pharma admits only that it will not contest venue for the purposes of this action only. With respect to any remaining allegations of Paragraph 12, RK Pharma denies the same.

13. ANSWER: Paragraph 13 sets forth legal conclusions based on alleged activities to which no response is required. With respect to any remaining allegations of Paragraph 13, RK Pharma denies the same.

14. ANSWER: Paragraph 14 states a legal conclusion to which no response is required. To the extent an answer is required, RK Pharma will not contest personal jurisdiction solely for the purposes of Plaintiffs' Complaint in this action only. With respect to any remaining allegations of Paragraph 14, RK Pharma denies the same.

BACKGROUND

15. ANSWER: ARI holds New Drug Application (“NDA”) No. 209379 for Selenious Acid ((1) eq.600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL), (2) eq. 60 mcg Selenium/mL (eq. 60 mcg Selenium/mL), and (3) eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL)), which was originally approved by the FDA on April 30, 2019. Defendant is otherwise without knowledge or information sufficient to form a belief as to the truth of the other allegations of Paragraph 15.

16. ANSWER: Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 16.

17. ANSWER: Defendant admits that Exhibit A to Plaintiffs’ Complaint contains what purports to be a copy of the ’957 patent. Defendant denies that the ’957 patent was “duly and legally issued” and denies any remaining allegations in Paragraph 17.

18. ANSWER: On information and belief, the ’957 patent has been listed in connection ARI’s Selenious Acid products in the FDA’s publication Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”).

19. ANSWER: On information and belief, as indicated in the Orange Book, the patent expiration date for the ’957 patent is July 1, 2041.

20. ANSWER: Denied.

21. ANSWER: Admitted.

22. ANSWER: RK Pharma admits that it was the named applicant and submitted the ANDA to FDA which contained a Paragraph IV Certification asserting that the ’565 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of the ANDA Products, or alternatively, that the ’565 patent is invalid. RK Pharma denies the remaining allegations in Paragraph 22.

23. ANSWER: Denied.

24. ANSWER: Defendant directs Plaintiff to the ANDA for its description of the ANDA Products and denies any remaining allegations.

25. ANSWER: Defendant directs Plaintiff to the ANDA for its description of the ANDA Products and denies any remaining allegations.

26. ANSWER: Defendant directs Plaintiff to the ANDA for its description of the ANDA Products and denies any remaining allegations.

27. ANSWER: Defendant directs Plaintiff to the ANDA for its description of the ANDA Products and denies any remaining allegations.

COUNT I
INFRINGEMENT OF THE '957 PATENT

28. ANSWER: Defendant repeats, reiterates and re-alleges the responses to paragraphs 1 through and including 27 of the Complaint with the same force and effect as if hereinafter set forth at length.

29. ANSWER: Paragraph 29 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Defendant RK Pharma denies the allegations of Paragraph 29.

30. ANSWER: RK Pharma cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions RK Pharma ultimately undertakes. To the extent an answer is required, RK Pharma denies the allegations of Paragraph 30.

31. ANSWER: RK Pharma cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions the RK Pharma ultimately undertakes. To the extent an answer is required, RK Pharma denies the allegations of Paragraph 31.

32. ANSWER: Paragraph 32 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Defendant RK Pharma denies the allegations of Paragraph 32.

33. ANSWER: Paragraph 33 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, RK Pharma denies the allegations of Paragraph 33.

34. ANSWER: Paragraph 34 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Defendant denies the allegations of Paragraph 34.

PRAYER FOR RELIEF

RK Pharma denies that Plaintiff is entitled to any of its requested relief.

AFFIRMATIVE DEFENSES

Defendant asserts the following defenses without prejudice to the denials in this Answer, without admitting any allegations of this Complaint not otherwise admitted.

FIRST AFFIRMATIVE DEFENSE **FAILURE TO STATE A CLAIM**

Plaintiff's Complaint, in whole or in part, fails to state claims upon which relief may be granted.

SECOND AFFIRMATIVE DEFENSE
INVALIDITY AND UNENFORCEABILITY

The '957 patent and each of the claims thereof, is invalid and/or unenforceable for failure to comply with one or more conditions for patentability and/or enforceability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidity and/or unenforceability.

THIRD AFFIRMATIVE DEFENSE
NO DIRECT INFRINGEMENT

Defendant does not infringe literally any valid and enforceable claim of the patent-in-suit and thus cannot be said to literally infringe the same. As no equivalent can be found in the ANDA Products for the missing elements of any of the claims of the patent-in-suit, there can be no infringement under the doctrine of equivalents.

FOURTH AFFIRMATIVE DEFENSE
NO INDIRECT INFRINGEMENT

Defendant has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the patent-in-suit, and the manufacturing, marketing, sale, offer for sale, importation, and/or distribution of the ANDA Products do not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the patent-in-suit.

FIFTH AFFIRMATIVE DEFENSE
NO COSTS

Plaintiff is barred by 35 U.S.C. § 288 from recovering any costs associated with this

suit.

SIXTH AFFIRMATIVE DEFENSE
FAILURE TO STATE CLAIM OF WILFULNESS

Plaintiff fails to state a proper claim for willful infringement or exceptional case under 35 U.S.C. §§ 271(e)(4) and 285, or otherwise.

SEVENTH AFFIRMATIVE DEFENSE
RESERVATION OF RIGHTS

Defendant reserves the right to assert additional defenses or counterclaims that discovery may reveal.

Dated: January 13, 2025

By: /s/ Eric I. Abraham

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